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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/096,648	06/12/1998	GYULA HADLACZKY	24601-402A	2049

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EXAMINER
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TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 04/09/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/096,648

Applicant(s)

HADLACZKY ET AL.

Examiner

Thai-An N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32,35,38,39,65,82,83,87,97-100 and 106-110 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32, 35, 38, 39, 65, 82, 83, 87, 97-100, 106-110 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/10/03, Paper No. 33, has been entered.

Applicants' Amendment, filed 1/10/03, Paper No. 34, has been entered.

Claims 32, 65, 82, 83 and 98 have been amended. Claims 33, 34, 36, 37, 43, 44, 59, 60, 71-74, 84-86, 88, 89 and 93-96 have been cancelled. Claims 106-110 have been newly added.

Claims 32, 35, 38, 39, 65, 82, 83, 87, 97-100, 106-110 are pending and under current examination.

Rejections made of record in the prior Office actions (Paper No. 24, 26 & 32) not made of record in the instant Office action have been withdrawn in view of Applicants' arguments, amendments to the claims.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the

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same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicant's arguments, see pp. 5-8 of the Response, filed 1/10/03, with respect to the rejection(s) of claim(s) 32, 35, 38, 39, 65, 82, 83, 87, 97-100, under 112, 1<sup>st</sup> ¶ have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and appears below.

Claims 32, 35, 38, 39, 65, 82, 83, 87, 97-100 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a transgenic non-human mammal comprising: introducing a cell comprising a SATAC, wherein the cell develops into an embryo in a female non-human mammal *of the same species*, and allowing the embryo to develop into a transgenic non-human mammal comprising the SATAC; and methods for producing a transgenic mouse, comprising introducing a mouse ES cell comprising a SATAC into a mouse embryo, introducing said embryo into a female *mouse* and allowing the embryo to develop into a transgenic *mouse* comprising said SATAC, does not reasonably provide enablement for methods for producing transgenic non-human mammal by introducing of a cell comprising a SATAC, wherein the cell develops into an embryo in a female non-human mammal of any species. The specification does not enable any person skilled in the art to which it pertains, or with which it is

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most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims as written encompass the implantation of embryos into surrogate mothers of different species, the state of the art of which is unpredictable. See claims 32, 99 and 106. For example, Fehilly *et al.* (*Nature*, Vol. 307, 16 February 1984) teach that often two unrelated species cannot carry a live hybrid fetus to term due to factors such as interspecific pregnancies, placental abnormalities and maternal immunological reaction against foreign antigens of the conceptus which would be the cause of immediate abortion (see p. 634, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph). Fehilly *et al.* summarize experiments for the production of such animals, and show an extremely low percentage of full term young (see Table 1, p. 635). Although Fehilly *et al.* show that is possible to produce embryos that have been implanted into surrogate mothers of a foreign species; it is clearly an unpredictable process.

Accordingly, in view of the state of the art, with regard to the unpredictability of implantation of embryos from foreign species into a surrogate mother, it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 32, 82 and 109 as written, are unclear. The claims recite that the cell comprising the SATAC is *capable of* developing into an embryo. As such, it is unclear whether this development actually occurs or that the cell could potentially develop. "Capable of" implies a latent property and the conditions for the latent property must be clearly defined. Therefore, it is unclear if the latent property is ever obtained. Claims 35, 38, 39, 65, 100, 108 depend from claim 32, claim 83, 87 depend from claim 82, claim 110 depends from claim 109.

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

Thái-An N. Ton  
Patent Examiner  
Group 1632

*Deborah Crouch*  
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GROUP 1600 7/6/30